PATENT COOPERATION TREATY

FEN021 - 228097

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
WILLIAM H. DIPPERT
WOLF, BLOCK, SCHORR & SOLIS-COHEN, LLP
250 PARK AVENUE
NEW YORK, NY 10177

PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Rule 71.1)

EMC-P

Date of mailing (*day/month/year*)		
Applicant's or agent's file reference 386/04133	**IMPORTANT NOTIFICATION**	
International application No. PCT/US04/25238	International filing date (*day/month/year*) 04 August 2004 (04.08.2004)	Priority date (*day/month/year*) 04 August '03 (04.08.2003)
Applicant VISION-SCIENCES, INC.		

1. The applicant is hereby notif ... rnational Preliminar ... smits herewi th the international preliminary r ... ternational application.

2. A copy of the report ar ... to the Internatio... unication to all the elected Offices.

3. Where require ... , the International Bureau will prepare an English translation of the report (b ... t ... xes ... transmit such translation to those Offices.

4. **REMI**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the *PCT Applicant's Guide.*

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed invention is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Linda C.M. Dvorak *T. Hurley for* Telephone No. 703-308-2193

Form PCT/IPEA/416 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
WILLIAM H. DIPPERT
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NEW YORK, NY 10177

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NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
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(PCT Rule 71.1)

Date of mailing *(day/month/year)*	29 NOV 2006

Applicant's or agent's file reference	IMPORTANT NOTIFICATION
386/04133	

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US04/25238	04 August 2004 (04.08.2004)	04 August 2003 (04.08.2003)

Applicant

VISION-SCIENCES, INC.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

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Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450	Linda C.M. Dvorak Telephone No. 703-308-2193
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Form PCT/IPEA/416 (January 2004)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
386/04133		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US04/25238	04 August 2004 (04.08.2004)	04 August 2003 (04.08.2003)
International Patent Classification (IPC) or national classification and IPC		
IPC: **A61B 1/00**(2006.01) USPC: 600/121		
Applicant		
VISION-SCIENCES, INC.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *(sent to the applicant and to the International Bureau)* a total of 9 sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) ____ , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
   - ☒ Box No. I Basis of the report
   - ☐ Box No. II Priority
   - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - ☐ Box No. IV Lack of unity of invention
   - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - ☐ Box No. VI Certain documents cited
   - ☐ Box No. VII Certain defects in the international application
   - ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
06 June 2005 (06.06.2005)	15 February 2006 (15.02.2006)
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Linda C.M. Dvorak Telephone No. 703-308-2193

Form PCT/IPEA/409 (cover sheet)(April 2005)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US04/25238

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

☐ the international application in the language in which it was filed.

☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3 and 23.1(b))

☐ publication of the international application (under Rule 12.4(a))

☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☐ the international application as originally filed/furnished

☒ the description:
pages 1-27 as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____

☒ the claims:
pages NONE as originally filed/furnished
pages* 28-36 as amended (together with any statement) under Article 19
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____

☒ the drawings:
pages 1/9 - 9/9 as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/figs _____
☐ the sequence listing (*specify*): _____
☐ any table(s) related to the sequence listing (*specify*): _____

4 ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/figs _____
☐ the sequence listing (*specify*): _____
☐ any table(s) related to the sequence listing (*specify*): _____

** If item 4 applies, some or all of those sheets may be marked "superseded."*

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 9,22,28,51-55,61,62 and 66	YES
	Claims 1-8,10-21,23-27,29-50,56-60,63-65 and 67-75	NO
Inventive Step (IS)	Claims 9,56,66	YES
	Claims 1-8,10-55,57-65 and 67-75	NO
Industrial Applicability (IA)	Claims 1-75	YES
	Claims NONE	NO

2. Citations and Explanations (Rule 70.7)

Please See Continuation

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**

Continuation of:

Claims 1-8,12-21,23-24,27,29-34,36-50,56-60 and 63-75 lack novelty under PCT Article 33(2) as being anticipated by U.S. Patent No. 5,025,778 to Silverstein et al.

Silverstein et al. disclose a tubing having a radially flexible wall coupled to said insertion tube, wherein the tubing has a variable cross-sectional area and is capable of providing a potential channel in an endoscope insertion. Silverstein et al. disclose a device for selectively stiffening a portion of the insertion tube while it is being inserted into the body or after it has been inserted into the body. The tubing is sufficiently flexible to be totally collapsed so that its cross-sectional area is approximately that of the wall of the tubing. The channel of the tubing is radially expandable to provide a lumen sufficiently large for matter to pass therethrough. The channel extends along an insertion tube into the body to permit medical devices to pass therethrough and to the body. A plurality of such flexible tubings, each having a respective channel, may be positioned around the outer circumference of the insertion tube. Furthermore, Silverstein et al. disclose numerous methods or devices may be used to expand the tubing. A rigid (but flexible) rod may be insertable into the channel to expand the tubing. A noncollapsible tubing may be carried by the rod into the flexible tubing and remain in the flexible tubing to prevent it from collapsing after the rod is removed. Any selected medical device may then be passed through the tubing to the tip of the endoscope for medical uses. In one embodiment, a plurality of flexible tubings are provided around the insertion tube to permit a plurality of medical devices to extend through the tubings simultaneously for use in a cooperative relationship. Alternatively, the flexible tubing may be expanded by forcing fluid under pressure into the tubing. The bending characteristics of the insertion tube may be changed by inserting a rod into the tubing a selected length. Alternatively, the bending characteristics of the insertion tube may be varied by pumping a fluid under a selected pressure into the tubing over a selected length or portion of the insertion tube. This can be the entire length. The proximal portion (close to the examiner) or another portion of the insertion tube closer to the tip may be selectively stiffened without stiffening either the proximal or distal tip (see Cols. 2-3 and Figs 1-6).

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US04/25238

Supplemental Box

Claims 1-7,13-18,23-24,27,33-34 and 63-65 lack novelty under PCT Article 33(2) as being anticipated by U.S. Patent No. 5,503,616 to Jones.

Jones discloses a smaller scope to gain access to a body cavity. Once access has been gained it is usually a simple procedure to dilate the cavity or orifice to allow entry of larger instruments or devices. The endoscope includes an elongated, substantially cylindrical portion having a first distal end and a second proximal end. The channel system comprises a collapsible channel with a first distal end and a second proximal end and is adapted to extend alongside and exterior to the cylindrical portion of the endoscope. The collapsible channel is provided with an access means communicating between the first end and the second end of the collapsible channel. The system also includes a means to attach the collapsible channel to the endoscope. Further, the collapsible access channel of the present invention provides a means to allow more and/or larger instruments to be placed in a body cavity. An endoscope with the attached access channel in collapsed form is first inserted into the body orifice. After insertion an instrument, generally in the form of a tube or a biopsy mechanism, may be inserted into the access channel. As the instrument is moved along the access channel, the elasticity of the channel enables the channel to enlarge and conform to and fit the instrument. The body orifice also naturally dilates to conform to the enlarged access channel. The collapsible channel, therefore, provides a variable sized entrance into the body orifice depending upon the medical procedures that are required see Col. 3, Line 22 - Col 4, Line 36).

Claims 1-6,10-11,24-26,31 and 33-36 lack novelty under PCT Article 33(2) as being anticipated by U.S. Patent No. 6,461,294 to Oneda et al.

Oneda et al. disclose an apparatus and methods for attaching and forming enclosed inflatable members on an endoscope assembly with a disposable sheath. A flexible and resilient cuff member is positioned on the outer surface of the disposable sheath and sealably and fixedly bonded to the sheath cover material at the cuff edges to form an annular space capable of inflation. The inflatable member formed thereby is inflated through a lumen internal to the sheath that has an opening into the interior annular space. In another aspect, the annular space may be divided into separate inflatable lobes. In still another aspect, the cuff member is a flexible and resilient enclosed member that is substantially toroidal in shape that is positioned on the outer surface of the sheath. In a further aspect, the inflatable member is formed from an excess length of sheath cover material disposed on the disposable sheath. A single reentrant fold of sheath material is formed with an edge that is sealably and fixedly bonded to the sheath cover material to form an annular space capable of inflation. In alternate aspects, the excess length of cover material may be used to form members with dual reentrant folds that comprise inflatable members with single and dual inflatable lobes (see Col. 2, Line 52 - Col. 3, Line 7 and Col. 5, Line 38-67).

Claims 22,28,51-55, and 61-62 lack an inventive step under PCT Article 33(3) as being obvious over U.S. Patent No. 5,025,778 to Silverstein et al. in view of U.S Patent No. 6,385,200 to Grossi.

Silverstein et al. disclose a sheath apparatus having a channel for use with an endoscope but is silent with respect to placing an electrode is mounted on an external surface of the channel tube. Grossi teaches of an analogous device having an electrode 18 and an electrode guide channel 68 wherein the device is capable of coagulation techniques well known in the art (see Col. 3, Lines 20-65). It would have been obvious to one skilled in the art at the time the invention was made to mount an electrode on the sheath of Silverstein et al. in order to provide a coagulating tool which is readily cheap, disposable and easy to use as taught by Grossi and is well known in the art.

Claims 1-75 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

Response to Arguments:

Applicant's arguments filed August 4, 2004 have been fully considered but they are not persuasive.
The term "substantially" in claims 1, 24, 30 and 33 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. As broadly as claimed the devices of both Silverton and Jones have a channel tube that can be moved between the closed and open states without substantially changing a length of a perimeter of the channel tube.
Applicant states that both Silverton and Jones fail to teach of a channel tube that is non-elastic. However, Silverstein shows an embodiment of a non-elastic tube as seen in Fig. 12.
Applicant states that Oneda et al. does not disclose channel running at least a portion of the sheath assembly. As broadly as claimed, Oneda et al. clearly show at least one channel tube openable into an open state wherein the tube defines a channel that extends along at least a portion of the sheath assembly (see Figs 1-4).
As broadly as claimed, Silverstein discloses an internal and external sheath being directly connected to each other (see Figs. 3a-b).
As broadly as claimed, Silverstein discloses a flexible sheath that can be selectively stiffened and which is capable of not having an aperture (see Col.3, Lines 1-13).
As broadly as claimed, Silverstein discloses a endoscopic tube defining a channel with a variable transverse extent (see Figs. 1-4) and is capable of inserting a working tube into a channel along a guide wire (see Col. 7, Lines 1-55).

CLAIMS

1. A sheath assembly for an invasive probe, comprising:

an internal sheath for covering a probe; and

at least one channel tube external to the internal sheath, the channel tube being foldable into a closed state in which the tube does not define a channel, or openable into an open state in which the tube defines a channel that extends along at least a portion of the sheath assembly, without substantially changing a length of a perimeter of the channel tube.

2. A sheath assembly according to claim 1, wherein the channel tube when in a closed state does not unfold from the closed state absent an external force.

3. A sheath assembly according to claim 2, wherein the channel tube is folded in an unorganized manner in the closed state.

4. A sheath assembly according to claim 2, wherein the channel tube is folded in an organized manner in the closed state.

5. A sheath assembly according to claim 2, wherein the channel tube is pleated in the closed state.

6. A sheath assembly according to claim 2, wherein the channel tube is folded over the internal sheath, in the closed state.

7. A sheath assembly according to any of claims 1-6, wherein the channel tube is self-collapsible, such that it does not remain in the open state, without a force not due to the channel tube that holds it in the open state.

8. A sheath assembly according to any of claims 1-6, wherein the channel tube does not self-collapse out of the open state, unless an external force is applied to the channel tube.

9. A sheath assembly according to claim 8, wherein the channel tube is deformed in a manner which prevents self-collapsing out of the open state.

10. A sheath assembly according to any of claims 1-6, wherein the channel tube is heat-set in the closed state so as to remain in the closed state until being moved to the open state.

11. A sheath assembly according to any of claims 1-6, wherein the channel tube is held in the closed state by an adhesive so as to remain in the closed state until being moved to the open state.

12. A sheath assembly according to any of claims 1-6, wherein the channel tube surrounds the internal sheath.

13. A sheath assembly according to any of claims 1-6, wherein the tube does not surround the internal sheath.

14. A sheath assembly according to any of claims 1-6, wherein the channel tube is directly attached to the internal sheath.

15. A sheath assembly according to claim 14, wherein over most of the length of the sheath assembly the external sheath is not attached to the internal sheath.

16. A sheath assembly according to claim 14, wherein over most of the length of the sheath assembly the external sheath is attached to the internal sheath along at least one longitudinal line.

17. A sheath assembly according to any of claims 1-6, wherein the channel tube and the internal sheath are connected, separately, to a proximal connector.

18. A sheath assembly according to any of claims 1-6, wherein the channel tube is formed with an internal notch adapted to receive a dovetail of a working tube.

19. A sheath assembly according to any of claims 1-6, wherein the channel tube does not have an aperture at its distal end.

20. A sheath assembly according to any of claims 1-6, wherein the channel tube has an aperture leading out of the sheath assembly, along its length.

21. A sheath assembly according to any of claims 1-6, wherein the channel tube is formed with a foldable lobe of a limited axial extent relative to the channel tube, mounted on the channel tube and open to the channel defined by the channel tube.

22. A sheath assembly according to any of claims 1-6, comprising an electrode mounted on an external surface of the channel tube.

23. A sheath assembly according to any of claims 1-6, wherein the at least one channel tube extends over at least 50% of the internal sheath.

24. An invasive tool, comprising:

an elongate probe; and

at least one flexible channel tube, for coupling to the elongate probe, the channel tube being foldable into a closed state in which the tube does not define a channel, or openable into an open state in which the tube defines a channel that extends along at least a portion of the elongate probe~~sheath assembly~~, without substantially changing a length of a perimeter of the channel tube,

wherein the channel tube is held in the closed state, absent a force that moves the channel tube to the open state.

25. An invasive tool according to claim 24, wherein the channel tube is heat set in the closed state.

26. An invasive tool according to claim 24, wherein the channel tube is fixed in the closed state by an adhesive.

27. An invasive tool according to claim 24, comprising an internal sheath slid over the elongate probe and wherein the at least one channel tube is attached to an external surface of the internal sheath.

28. An invasive tool according to any of claims 24-27, comprising an electrode mounted on an external surface of the channel tube.

29. An invasive tool according to any of claims 24-27, wherein the channel tube is non-elastic.

30. A channel add-on for an invasive probe, comprising:

at least one channel tube, for coupling to an invasive probe, which is foldable into a closed state in which the tube does not define a channel, or openable into an open state in which the tube defines a channel, without substantially changing a length of a perimeter of the channel tube; and

means for opening the tube into the open state while the tube is within the patient.

31. A channel according to claim 30, wherein the means for opening the tube comprise means for dissolving an adhesive.

32. A channel according to claim 30, wherein the means for opening the tube comprise means for injecting a fluid into the tube.

33. A method of providing an endoscopic channel, comprising:

inserting into a patient, a probe with a sheath assembly including a channel tube being foldable into a closed state in which the tube does not define a channel, or openable into an open state in which the tube defines a channel that extends along at least a portion of the sheath assembly, without substantially changing a length of a perimeter of the channel tube; and

opening the tube into the open state while the tube is within the patient.

34. A method according to claim 33, wherein opening the tube into the open state comprises inserting a working tube or a tool into the tube.

35. A method according to claim 33, wherein opening the tube into the open state comprises dissolving an adhesive holding the tube folded.

36. A method according to claim 33, wherein opening the tube into the open state comprises injecting a fluid into the tube.

37. A method according to any of claims 33-36, wherein inserting the probe comprises inserting while the channel tube is held in the closed state.

38. A method according to any of claims 33-36, wherein inserting the probe comprises inserting while the channel tube is not held in any specific state.

39. A method according to any of claims 33-36, wherein the channel tube surrounds the probe.

40. A method according to any of claims 33-36, wherein inserting the probe comprises inserting a probe surrounded by an internal sheath.

41. A method according to any of claims 33-36, wherein the channel tube dopes not remain in the open state, unless an external force keeps it in the open state.

42. A method according to any of claims 33-36, wherein the channel tube does not self-collapse out of the open state, unless an external force is applied to the channel tube.

43. A sheath assembly for a probe, comprising:

an internal sheath configured to isolate a probe from body fluids; and

an external sheath surrounding the internal sheath, the internal and external sheaths being directly connected to each other.

44. A sheath assembly according to claim 43, wherein the internal and external sheaths are connected to each other over at least one axial line extending over a segment of the length of the sheaths.

45. A sheath assembly according to claim 44, wherein the internal and external sheaths are connected over at least two longitudinal lines, so as to define a plurality of separate channels between the sheaths.

46. A sheath assembly according to claim 43, wherein the internal and external sheaths are connected non-symmetrically radially.

47. A sheath assembly according to claim 43, wherein the internal and external sheaths are connected radially symmetrically.

48. A sheath assembly according to any of claims 43-47, wherein the internal and external sheaths are connected substantially only at a plurality of circumferential points at a distal end of the external sheath.

49. A sheath assembly according to any of claims 43-47, wherein the internal and external sheaths coextend at their distal ends, such that their distal ends extend to a same point.

50. A sheath assembly according to any of claims 43-47, wherein the internal sheath extends beyond the distal end of the external sheath.

51. A sheath assembly for a probe, comprising:

an intermediate flexible sheath configured to define a first channel between the probe and the intermediate sheath; and

an external sheath adapted to define a second channel between the intermediate sheath and the external sheath.

52. A sheath assembly according to claim 51, comprising a proximal port connected to the first channel.

53. A sheath assembly according to claim 51, comprising an internal sheath configured to isolate the probe from body fluids.

54. A sheath assembly according to any of claims 51-53, wherein at least one of the intermediate sheath and the external sheath is stretchable so as to define the respective channel.

55. A sheath assembly according to any of claims 51-53, wherein at least one of the intermediate sheath and the external sheath includes loose material that can be unfolded to define the respective channel.

56. A sheath assembly for a probe, comprising:
an internal sheath for covering an elongate probe;
a channel tube with a variable transverse extent, external to the internal sheath; and
a nozzle connected to the distal end of the channel tube.

57. A sheath assembly according to claim 56, wherein the channel tube comprises a foldable channel.

58. A sheath assembly according to claim 56, wherein the channel comprises a stretchable channel.

59. A sheath assembly according to any of claims 56-58, wherein the nozzle is directed in a direction substantially different from the main axis of the distal end of the channel.

60. A sheath assembly according to any of claims 56-58, comprising a window at the distal end of the internal sheath and wherein the nozzle is directed in a direction suitable for flushing the window.

61. A sheath assembly for a probe, comprising:
an internal sheath for covering an elongate probe; and
a channel tube with a variable transverse extent, external to the internal sheath, the channel tube not having an aperture at its distal end.

62. A sheath assembly according to claim 61, comprising one or more holes along an axial length of the channel tube.

63. A sheath assembly, comprising:
an endoscopic tube defining a channel with a variable transverse extent, including a longitudinal notch formed in the tube; and

a working tube comprising a protrusion adapted to fit into the notch.

64. A sheath assembly according to claim 63, wherein the protrusion has a dovetail shape.

65. A sheath assembly according to claim 63, wherein the tube comprises a foldable tube.

66. A sheath assembly according to any of claims 63-65, wherein the tube comprises an inflatable tube.

67. A method of inserting a working tube into a channel, comprising:

providing a guide wire within the channel; and

inserting the working tube into the channel along the guide wire, while the channel is within a patient.

68. A method according to claim 67, wherein providing the guide wire comprises providing the guide wire in the channel before the channel is inserted into the patient.

69. A method according to claim 67, wherein providing the guide wire comprises providing the guide wire in the channel after the channel is inserted into the patient.

70. A method according to any of claims 67-69, wherein providing the guide wire comprises providing the guide wire such that both ends of the guide wire extend out of a proximal end of the channel.

71. A method according to any of claims 67-69, wherein providing the guide wire comprises providing a guide wire that is anchored to a distal end of the channel.

72. A method according to any of claims 67-69, wherein providing the guide wire comprises providing a guide wire that is threaded through a distal end of the channel.

73. A sheath assembly according to claim 1, wherein the channel tube is non-elastic.

74. An invasive tool according to claim 30, wherein the channel tube is non-elastic.

75. A method according to claim 33, wherein the channel tube is non-elastic.